K070225
p. 1 of 3

DEC 1 3 2007

Section 5.0- 510(k) Summary
(Prepared in accordance with 21 CFR Part 807.92)

a. Submitted

Applicant Name:	ABIOMED, Inc. 22 Cherry Hill Drive, Danvers, MA 01923
Contact Person:	Robert T.V. Kung, Ph.D.
Date Summary Prepared:	December 7, 2007

b. Device information

Trade Name:	iPulse Intra-Aortic Balloon Pump Console
Common Name:	Intra-Aortic Balloon Pump
Classification Name:	Intra-Aortic Balloon and Control System (Class III under CFR870.3535)
Product Code:	74DSP

c. Legally Marketed Predicate Devices

Datascope CS100 Intra-Aortic Balloon Pump (K031636)

Arrow AutoCAT2 Intra-Aortic Balloon Pump (K002256)

d. Device Description:

The iPulse Intra-Aortic Balloon Pump (IABP) Console is a cardiac assist device. It supports the heart's left ventricle by increasing coronary perfusion and reducing left ventricular work. The iPulse IABP Console is designed to work in conditions which are unique to the operating room, catheterization laboratory, critical care unit and during transport. The iPulse IABP Console has two operation modes; auto and manual. The auto operation mode provides simplicity and minimizes operator intervention. The manual operation mode provides operators with flexibility for difficult clinical cases.

e. Intended Use:

The iPulse IABP Console can be used to provide temporary support to the left ventricle via the principle of counter-pulsation. An intra-aortic balloon (IAB) catheter is placed in the descending aorta, just distal to the left subclavian artery. Once the IAB is positioned, the iPulse IABP Console is adjusted to trigger in synchrony with either the ECG or arterial pressure waveform to ensure that inflation and deflation occur at the appropriate points during the cardiac cycle. The iPulse IABP Console is intended for use in health care facilities to improve cardiovascular functioning during the following situations:

- Unstable refractory angina
- Impending infarction
- Post Infarction Angina or Threatening Extension of Myocardial Infarction
- Refractory ventricular failure

- Mechanical complications because of myocardial infarction
- Cardiogenic shock
- Support and stabilization of high risk patients undergoing diagnostic and non-surgical procedures
- Ischemic related intractable ventricular arrhythmias
- Septic shock
- Interoperative pulsatile flow generation
- Weaning from cardiopulmonary bypass
- Cardiac support for high risk surgical patients and coronary angiography and angioplasty patients
- Prophylactic support in preparation for cardiac surgery
- Post-surgical myocardial dysfunction
- Cardiac Contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects
- Support for failed angioplasty and valvuloplasty

f. Technological Characteristics and Comparison to Predicate Device(s):

The iPulse IABP Console is an electro-mechanical system used to inflate and deflate 8 French, 40 cc intra-aortic balloon catheters. The iPulse console and the predicate consoles have equivalent performance for counter-pulsation therapy

Table 1 provides a comparison of the iPulse IABP Console with the with predicate IABP consoles. This table illustrates the equivalency of the iPulse IABP Console with its predicates.

Table 1- Comparison Table for iPulse IABP Console

Property	**iPulse Console**	**CS100 Console- *K031636***	**AutoCAT2 Console- *K002256***
Intended Duration of Use	Temporary use: Approx. ≤ 30 days	Temporary use: Approx. ≤ 30 days	Temporary use: Approx. ≤ 30 days
IAB Catheter Tested	8F, 40 cc	8F, 40 cc	8F, 40 cc
IABP Drive System	Electro-pneumatic with replaceable helium cylinder	Electro-pneumatic with replaceable helium cylinder	Electro-pneumatic with replaceable helium cylinder
User Interface/Display Type	Laptop	Laptop	Laptop
Maximum Beat Rate	200 BPM	185 BPM	200 BPM
Trigger Signals Accepted	ECG, Aortic pressure	ECG, Aortic pressure	ECG, Aortic pressure
Console Size (on Cart)	30"Hx23"Wx11"D	26.6"Hx20.5"Wx10.8"D	37.8"Hx14"Wx20"D
Console Weight	126 lbs	126 lbs	86 lbs
Voltage Requirement	120/240 Vac	120/240 Vac	120/240 Vac
Battery Type	Sealed Lead Acid	Sealed Lead Acid	Sealed Lead Acid
Battery Runtime (minimum)	2.5 hours	2.25 hours	2.0 hours

g. Pre-clinical Test Results:

Three different types of pre-clinical testing were completed for the iPulse IABP Console: laboratory, software verification and electrical standards testing. The laboratory tests demonstrated equivalence to the 2 predicate IABP consoles, and included performance and reliability testing in accordance with the FDA's recommendations, as provided in: "Guidance for the Preparation and Content of Applications to the Food and Drug Administration for Determining the Equivalence of Intra-Aortic Balloon Catheters and Consoles under the 510(k) Regulations", Preliminary Draft, 12/9/93. The software verification and electrical standards (EMI, EMC and Electrical Safety) testing demonstrated compliance with the applicable standards required for device clearance.

The pre-clinical test results demonstrate that the iPulse IABP Console is safe and effective, and performs equivalently to the 2 predicate IABP consoles.

h. Conclusion:

Based on the information presented in this 510(k) pre-market notification, the iPulse IABP Console is considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

Abiomed, Inc.
c/o Dr. Robert T.V. Kung
Senior Vice President
Chief Scientific Officer
22 Cherry Hill Drive
Danvers, MA 01923

Re: K070225
iPulse IABP Console
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-aortic Balloon and Control System
Regulatory Class: Class III
Product Code: DSP
Dated: December 7, 2007
Received: December 10, 2007

Dear Dr. Kung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070225

Device Name: iPulse Intra-aortic Balloon Pump Console

Intended Use:

The iPulse IABP Console is an electromechanical system used to inflate and deflate 8F 40 cc intra-aortic balloons (IABs). It provides temporary support to the left ventricle via the principle of counterpulsation. For this therapy, the IAB is placed in the descending aorta, just distal to the left subclavian artery. After positioning the balloon, the user can adjust the balloon to trigger in synchrony with either the ECG or arterial pressure waveform to ensure that both inflation and deflation occur at the proper point during the cardiac cycle.

Indications for Use:

Appropriate patient groups for IAB counterpulsation therapy using the iPulse IABP Console are adults suffering from:

- Unstable refractory angina
- Impending infarction
- Post Infarction Angina or Threatening Extension of Myocardial Infarction
- Refractory ventricular failure
- Mechanical complications because of myocardial infarction
- Cardiogenic shock
- Support and stabilization of high risk patients undergoing diagnostic and non-surgical procedures
- Ischemic related intractable ventricular arrhythmias
- Septic shock
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- Cardiac support following correction of anatomical defects
- Support for failed angioplasty and valvuloplasty

Prescription Use __X__ *AND/OR* *Over-The-Counter Use* _____
(Part 21 CFR 801 Subpart D) *(21 CFR 807 Subpart C)*

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K070225

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070225